UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

MIA INEZ SMITH, individually and as successor-in-interest to MICHAEL RAY SMITH, deceased; and MAKIA RAQUEL SMITH, individually, and successor-in-interest to MICHAEL RAY SMITH, deceased,

Plaintiffs,

v.

MEDTRONIC, INC.; MEDTRONIC USA, INC.; COVIDIEN LP; COVIDIEN SALES LLC; and DOES 1 to 50,

Defendants.

Case No. 22-cv-09179-JSW

ORDER DENYING MOTION TO DISMISS

Re: Dkt. No. 15

Now before the Court is the motion to dismiss the first amended complaint filed by Defendants Medtronic, Inc., Medtronic USA, Inc., Covidien LP, and Covidien Sales LLC (collectively, "Defendants"). The Court has considered the parties' papers, relevant legal authority, and the record in this case. For the reasons that follow, the Court DENIES Defendants' motion to dismiss.

BACKGROUND

Mia Inez Smith and Maki Raquel Smith ("Plaintiffs"), daughters of Michael Ray Smith, Deceased ("Decedent") initiated this action by filing a complaint in the Superior Court of California, County of Alameda, on November 15, 2022. (Dkt. No. 1-1.) Defendants timely

removed this action on December 30, 2022. (Dkt. No. 1.) Thereafter, on January 20, 2023, Plaintiffs filed their first amended complaint ("FAC"). (Dkt. No. 13.) On February 10, 2023, Defendants moved to dismiss pursuant to Federal Rules of Civil Procedure 8(a)(2) and 12(b)(6) for failure to state a claim upon which relief can be granted.[1]

According to the amended complaint, on March 7, 2022, Decedent underwent video-assisted thoracoscopic surgery at Highland Hospital in Oakland, California, during which the operating surgeon used a l-hook ligature device (the "Device"). (*Id.* ¶¶ 1, 2.) During the surgery, which was converted to an open left thoracotomy, repair of cardiac injury, and resection of mediastinal mass, the Device "suddenly and unexpectedly broke, cracked, fractured and/or otherwise failed." (*Id.* ¶ 2.) This caused an avulsion injury to Decedent's left anterior descending artery and caused bleeding, injury, and other damage. (*Id.*) The surgery was "complicated by [the Device's] fracture interoperatively and [caused] 2L intraoperative blood loss with injury to left anterior descending branch requiring ligation and subsequent respiratory acidosis, shock, [and] AKI with hyperkalemia." (*Id.* ¶ 21.)

Plaintiffs further allege that the Device was only cleared for sale under Section 510(k) of the Medical Device Act Amendments ("MDA"), based on an abbreviated process for securing clearance from the United States Food and Drug Administration ("FDA"). (*Id.* ¶¶ 13-16.) Plaintiffs contend that the abbreviated process "allows manufacturers to secure FDA clearance by merely showing that a device is 'substantially equivalent' to a device already on the market, i.e., a 'predicate device' which literally may not ever have gone through any significant FDA evaluation/analysis." (*Id.* ¶ 15.) Plaintiffs allege that Defendants submitted the Device for Section 510(k) pre-market clearance on June 30, 2016, and on September 16, 2016, the FDA issued a clearance letter for the Device "based on a substantial equivalence to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, *not efficacy or safety*." (*Id.* ¶¶ 13, 16.) Plaintiffs allege that the FDA expressly included in its clearance letter for the Device that "'FDA's issuance of a substantial equivalence determination does not mean that FDA has made a

[1] Plaintiffs filed their opposition 17 days later, in violation of Northern District Local Rule 7-3(a). The Court will address the motion on the merits notwithstanding the opposition was late-filed.

determination that your device complies with other requirements of the [MDA] or any Federal statutes and regulations administrated by other Federal agencies." (*Id.* ¶ 16.)

Plaintiffs assert that a "health professional company representative of Defendants was present" during Decedent's surgery on March 7, 2022. (*Id.* ¶ 17.) Plaintiff further contend that the representative reported to the FDA on July 1, 2022, that during the surgery, the Device "split from the handle half way down the outside sleeve." (*Id.* ¶ 18.) Plaintiffs allege that during the surgery, the Device "broke with a sharp edge at the fracture site noted during removal" and "fractured intraoperatively causing injury to [Decedent]'s left anterior descending artery." (*Id.* ¶¶ 19, 20.)

As a result of the Device breaking unexpectedly, Plaintiffs allege that Decedent suffered "conscious pain and suffering for the remainder of his life, and ultimately died as a result of his injuries on March 19, 2022." (*Id.* ¶¶ 3, 23.) Following the death of their father, as successors in interest, Plaintiffs filed suit for (1) strict products liability – manufacturing defect and failure to warn and (2) negligent products liability – (A) negligent design, manufacturing, and sale; (B) failure to recall/retrofit; and (C) failure to warn. Defendants move to dismiss on the basis that the first amended complaint fails to state well-pleaded facts giving rise to a plausible claim for relief.

ANALYSIS

A. Applicable Legal Standards.

A motion to dismiss is proper under Rule 12(b)(6) where the pleadings fail to state a claim upon which relief can be granted. A court's "inquiry is limited to the allegations in the complaint, which are accepted as true and construed in the light most favorable to the plaintiff." *Lazy Y Ranch Ltd. v. Behrens*, 546 F.3d 580, 588 (9th Cir. 2008). Even under the liberal pleading standard of Rule 8(a)(2), "a plaintiff's obligation to provide the 'grounds' of his 'entitle[ment] to relief' requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (citing *Papasan v. Allain*, 478 U.S. 265, 286 (1986)).

Pursuant to *Twombly*, a plaintiff cannot merely allege conduct that is conceivable but must instead allege "enough facts to state a claim to relief that is plausible on its face." *Id.* at 570. "A

claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citing *Twombly*, 550 U.S. at 556). "The plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." *Id.* (quoting *Twombly*, 550 U.S. at 556).

If the allegations are insufficient to state a claim, a court should grant leave to amend unless amendment would be futile. *See, e.g.*, *Reddy v. Litton Indus., Inc.*, 912 F.2d 291, 296 (9th Cir. 1990); *Cook, Perkiss & Liehe, Inc. v. Northern Cal. Collection Serv. Inc.*, 911 F.2d 242, 246-47 (9th Cir. 1990).

B. Strict Products Liability Claim – Manufacturing Defect.

A plaintiff may seek recovery for products liability based on either a theory of strict liability or a theory of negligence. Under both theories, plaintiff must ultimately prove that the defect caused the injury. *Trejo v. Johnson & Johnson*, 13 Cal. App. 5th 110, 117 (2017). Claims premised on strict liability theory, unlike claims premised on negligence, do not require plaintiff to prove that the defendant was negligent in causing the injury. *Brown v. Superior Court*, 44 Cal. 3d 1049, 1056 (1988). Rather, the burden of proof is eased under a under strict liability theory. *Id.* "[O]ne of the principal purposes behind the strict liability doctrine is to relieve an injured plaintiff of many of the onerous evidentiary burdens inherent in a negligence cause of action." *Barker v. Lull Engineering Co.*, 20 Cal. 3d 413, 431 (1978). The strict liability test for defective design "subjects the manufacturer to liability whenever there is something 'wrong' with its product design either because the product fails to meet ordinary consumer expectations as to safety or because, on balance, the design is not as safe as it should be while stopping short of making the manufacturer an insurer for all injuries which may result from the use of its product." *Id.* at 432.

California recognizes strict liability for product defects in manufacturing. *See Anderson v. Owens-Corning Fiberglass Co.*, 53 Cal. 3d 987, 995 (1991). To state a claim under strict liability theory for a manufacturing defect, a plaintiff must allege the following elements: "(1) he has been injured by the product; (2) the injury occurred because the product was defective; and (3) the defect existed when the product left the hands of the defendant." *Nichols v. Covidien LP*, No. 20-

cv-06836-EMC, 2021 WL 764134, at *3 (N.D. Cal. Feb. 26, 2021) (citations omitted). Here, in Plaintiffs' first cause of action, they allege manufacturing and warning defects. Under the manufacturing defect theory, a "manufacturing or production defect is readily identifiable because a defective product is one that differs from the manufacturer's intended result or from other ostensibly identical units of the same product line." *Barker*, 20 Cal. 3d at 429. The manufacturing defect analysis posits that "a suitable design is in place, but that the manufacturing process has in some way deviated from that design." *In re Coordinated Latex*, 99 Cal. App. 4th 594, 613 (2002).

Here, Plaintiffs have plausibly alleged the necessary components for a strict liability manufacturing defects claim. Plaintiffs allege that Defendants manufactured the Device and that it was defective when it left their possession, having only received a pre-market clearance based on "substantial equivalence to legally marketed predicate devices … *not efficacy or safety*." (FAC ¶ 16.) Plaintiffs allege that the Device and each of its component parts were not manufactured with "sufficient strength to protect against and/or prevent breaks … during foreseeable uses and/or misuses" and was therefore "unsafe for its intended use and reasonably foreseeable misuses" when it "suddenly and unexpectedly fractured at its shaft causing … injury." (*Id.* ¶¶ 27, 28.) Plaintiffs further allege that Decedent and his successors were injured and that the defective Device the substantial cause of Decedent's pain and suffering and eventual death, thereby causing harm to his successors. (*Id.* ¶¶ 12, 15, 16-23.)

Accordingly, Plaintiffs have met their burden at this procedural posture to plead sufficient facts to state a claim for manufacturing defects under a strict liability theory.

C. Negligent Products Liability Claim.

Plaintiffs also allege a cause of action for negligent products liability. A product's design is defective "if it either violates the minimum safety expectations of an ordinary consumer or contains dangers which outweigh its benefits." *Soule v. Gen. Motors Corp.*, 8 Cal. 4th 548, 570 n.7 (1994). The test for negligent design "involves a balancing of the likelihood of harm to be expected from a machine with a given design and the gravity of harm if it happens against the burden of the precaution which would be effective to avoid the harm." *Merrill v. Navegar, Inc.*, 26 Cal. 4th 465, 479 (2001).

Plaintiffs allege that prior to the Decedent's surgery, Defendants negligently designed and manufactured and sold the Device and failed to subject the product to adequate evaluation and testing, which, they assert, would have revealed the propensity of Device to break or otherwise fail under foreseeable uses and/or misuses. (*Id.* ¶ 33A.i.) Plaintiffs further allege that Defendants had received reports from consumers and healthcare providers indicating that the Device had caused serious complications and injuries when it broke, but Defendants "consciously decided not to perform any further testing … investigate the root cause of these complications; suspend sales and distribution; or warn physicians and patients of the propensity of the [Device] to break … or otherwise fail." (*Id.* ¶¶ 33A.ii, iii.) Plaintiffs contend that Defendants failed to recall or retrofit the Device when they were aware, prior to the Decedent's surgery, both that the Device was defective and the likelihood and severity of potential harm it may cause based on the number of complaints and additional available data about the Device. (*Id.* ¶¶ 33B.i, ii, iii.)

Accordingly, Plaintiffs have met their burden at this procedural posture to plead sufficient facts to state a claim for manufacturing defects under a negligent products liability theory.

D. Failure to Warn Under Strict Liability and Negligence Theories.

California law recognizes failure to warn claims under both strict liability and negligence theories. *Webb v. Special Elec. Co.*, 63 Cal. 4th 167, 181 (2016). A "product seller will be strictly liable for failure to warn if a warning was feasible and the absence of a warning caused the plaintiff's injury." *Id.* In particular in the scientific field, "manufacturers [are held] strictly liable for injuries caused by their failure to warn of dangers that were known in the scientific community at the time they manufactured and distributed their product." *Johnson v. Am. Standard, Inc.*, 43 Cal. 4th 56, 64 (2008).

Defendants contend that Plaintiffs fail to state a claim for failure to warn in light of California's learned intermediary doctrine. This doctrine provides that a manufacturer of prescription drugs or medical devices may satisfy its duty to warn when it provides adequate warnings to the prescribing physician, not to the patient. *See Brown*, 44 Cal. 3d at 1061 ("It is well established that a manufacturer fulfills its duty to warn if it provides adequate warning to the physician."). The learned intermediary doctrine applies under both the strict liability and

negligence theories. *See Zetz v. Boston Scientific Corp.*, 398 F. Supp. 3d 700, 706 (E.D. Cal. 2019) (citations omitted).

Here, Plaintiffs sufficiently allege that Defendants became aware of the defects in the Device prior to the surgery, including its propensity to break, and they failed to adequately warn physicians or instruct on the safe storage, uses, inspection, maintenance, cleaning, and repair of the Device. (FAC ¶¶ 27D-G, 33C.iii, v.) Plaintiffs allege that, prior to the surgery, the Device "had already caused numerous instances of surgical complications, pain, lacerations, avulsions, bleeding, suffering, injury and/or death by breaking … and Defendants consciously decided neither to warn physicians or patients." (*Id.* ¶ 33D.v.) Plaintiffs allege that as a direct and proximate result, Decedent and his successors suffered injuries, including wrongful death. (*Id.* ¶¶ 28, 29, 34-36.)

Accordingly, Plaintiffs have met their burden at this procedural posture to plead sufficient facts to state a claim for failure to warn under either the strict liability or negligence theories.[2]

CONCLUSION

For the reasons stated herein, the Court DENIES Defendants' motion to dismiss the first amended complaint. The Court FURTHER ORDERS the parties to appear for a case management conference on September 1, 2023, at 11:00 a.m. The parties shall file a joint case management conference statement by no later than August 25, 2023.

IT IS SO ORDERED.

Dated: July 28, 2023

JEFFREY S. WHITE
United States District Judge

[2] Lastly, Defendants argue that the amended complaint should be dismissed as impermissible shotgun pleading. "Shotgun pleadings are pleadings that overwhelm defendants with an unclear mass of allegations and make it difficult or impossible for defendants to make informed responses to the plaintiff's allegations." *Sollberger v. Wachovia Sec., LLC*, 2010 WL 2674456, at *4 (C.D. Cal. June 30, 2010). The Court finds Defendants' contention unpersuasive.